

(A) Customer order number;  
(B) Manufacturer's name and product code;

(C) Factory reel number and year of manufacture;

(D) Gauge of conductors and pair size of wire;

(E) Length of wire; and

(F) RUS designation letter "K."

(3) When CCSR and NMR aerial service wires are shipped in coils the following provisions shall apply:

(i) The diameter of the coil shall be large enough to prevent damage to the wire from coiling or uncoiling;

(ii) The nominal length of the wire in a coil shall be 305 meters (1,000 feet). No coil shall be less than 290 meters (950 feet) long or more than 460 meters (1,500 feet) long; however, 25 percent of the total number of coils may be less than 305 meters (1,000 feet);

(iii) The coils of wire shall be wound securely with strong tape in four separate evenly spaced places;

(iv) The coils may be protected from damage by wrapping the coil with heavy paper, burlap, or other suitable material accepted by RUS prior to its use. The use of the heavy paper, burlap, or other suitable means of protection shall be at the option of the manufacturer unless specified by the end user; and

(v) Each coil shall be tagged with the following information:

(A) Customer order number;

(B) Manufacturer's name and product code;

(C) Year of manufacture;

(D) Gauge of conductors and pair size of wire;

(E) Length of wire; and

(F) RUS designation letter "K."

(4) In lieu of wrapping the coil with heavy paper, burlap, or other suitable material, the coil may be packaged in a moisture resistant carton.

(5) When the coils are shipped in moisture resistant cartons, each carton shall be marked with the information specified in paragraphs (f)(3)(v)(A) through (f)(3)(v)(F) of this section.

(6) Other methods of shipment may be used if accepted by RUS prior to their use.

(7) When NMR aerial service wire is shipped, the ends of the wire shall be sealed in accordance with ANSI/ICEA S-89-648-1993, paragraph 9.2.

Dated: December 19, 1995.

Jill Long Thompson,  
*Under Secretary, Rural Economic and Community Development.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 888

[Docket No. 95N-0176]

#### Orthopedic Devices: Classification, Reclassification, and Codification of Pedicle Screw Spinal Systems; Extension of Comment Period

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Proposed rule; extension of comment period.

**SUMMARY:** The Food and Drug Administration (FDA) is extending to March 4, 1996, the comment period for the proposed rule that published in the Federal Register of October 4, 1995 (60 FR 51946). The document proposed to classify certain unclassified preamendments pedicle screw spinal systems into class II (special controls), and to reclassify certain postamendments pedicle screw spinal systems from class III (premarket approval) to class II. FDA is taking this action in response to several requests for an extension to assure adequate time for preparation of comments.

**DATES:** Written comments by March 4, 1996.

**ADDRESSES:** Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Mark N. Melkerson, Center for Devices and Radiological Health (HFZ-410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2036.

**SUPPLEMENTARY INFORMATION:** In the Federal Register of October 4, 1995 (60 FR 51946), FDA published a proposed rule to classify certain unclassified preamendments pedicle screw spinal systems into class II (special controls), and to reclassify certain postamendments pedicle screw spinal systems from class III (premarket approval) to class II. FDA is proposing to place certain pedicle screw spinal systems in class II because the agency believes that sufficient information exists to establish special controls to provide reasonable assurance of its safety and effectiveness.

Interested persons were invited to comment by January 2, 1996. FDA received several requests to extend the comment period, including a request from a United States District Court

Judge presiding over product liability actions concerning orthopedic bone screw products. The court requested that FDA allow a 60-day extension because court orders relating to the disclosure of certain information about pedicle screws may make it difficult for parties involved in the litigation to submit relevant information to FDA by January 2, 1996.

Because FDA wants to provide adequate time for the submission of all relevant information related to these important public health issues, FDA is extending the comment period for 60 days. Accordingly, FDA finds under section 520(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(d)) that there is good cause for such an extension.

Interested persons may, on or before March 4, 1996, submit to Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 21, 1995.

Joseph A. Levitt,

*Deputy Director for Regulations Policy, Center for Devices and Radiological Health.*

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## DEPARTMENT OF TRANSPORTATION

### Coast Guard

#### 33 CFR Parts 62 and 66

[CGD 94-091]

RIN 2115-AF14

#### Conformance of Uniform State Waterways Marking System and Western Rivers Marking System with the United States Aids to Navigation System and the Maritime Buoyage System of the International Association of Lighthouse Authorities

**AGENCY:** Coast Guard, DOT.

**ACTION:** Advance notice of proposed rulemaking and request for comments.

**SUMMARY:** The Coast Guard is considering changes that would bring the Uniform State Waterways Marking System (USWMS) and the Western Rivers Marking System (WRMS) more into conformance with the U.S. Aids to Navigation System (USATONS) and the

Maritime Buoyage System (MBS) of the International Association of Lighthouse Authorities (IALA). These changes would help mariners avoid misinterpreting signals they might see when transiting different bodies of water now subject to different marking systems.

**DATES:** Please submit comments on or before February 12, 1996.

**ADDRESSES:** Comments may be mailed to the Executive Secretary, Marine Safety Council (G-LRA, Room 3406) [CGD 94-091], U.S. Coast Guard Headquarters, 2100 Second Street SW., Washington, DC 20593-0001, or may be delivered to room 3406 at the same address between 8 a.m. to 3 p.m., Monday through Friday, except Federal holidays. the telephone number is (202) 267-1477.

The Executive Secretary maintains the public docket for this notice and request for comments. Comments will become part of this docket and will be available for inspection or copying at room 3406, U.S. Coast Guard Headquarters, between 8 a.m. to 3 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** LTJG Chad Asplund, Division of Short Range Aids to Navigation, Telephone: (202) 267-1386.

#### **SUPPLEMENTARY INFORMATION:**

##### **Request for Comments**

The Coast Guard encourages interested persons to participate in this notice and request for comments by submitting written data, views, or arguments. Persons submitting comments should include their names and addresses, identify this rulemaking [CG 94-091] and the specific section of this notice to which each comment applies, and give the reason for each comment. Please submit two copies of all comments and attachments in an unbound format, no larger than 8+ by 11 inches, suitable for copying and electronic filing. Persons wanting acknowledgement of receipt of comments should enclose stamped, self-addressed postcards or envelopes.

##### **Background and Purpose**

In 1966 the USWMS was created to provide a system that would adequately mark State waters. At its inception it was meant in part to supplement the USATONS. It offered two types of aids to navigation, a system of regulatory markers as well as a system to supplement the USATONS. It features red and black buoys to mark lateral hazards.

The WRMS was introduced to establish a system that would adequately mark the dynamic

waterways of the Mississippi River and its Western counterparts. Some deviations from the USATONS were necessary to adequately mark these waterways. The WRMS allowed for only a few light characteristics to mark the waterways. As the number of users increased, and as the number of aids increased, a need arose to differentiate among the aids in the WRMS.

In 1982, the United States, along with most of the world's other maritime Nations, became a party to the agreement that established the MBS of the IALA. In 1985 the United States began converting the USATONS to harmonize with the MBS; if finished in 1991. Yet the systems that mark the Uniform State Waterways and the Western Rivers are not fully in conformance with the single system comprising MBS and USATONS.

The purpose of this proposed change is to develop an approach to adequately mark the Uniform State Waterways and Western Rivers while minimizing the number of systems of aids to navigation.

The Coast Guard is considering the following changes:

1. Allowing the five existing flash characteristics authorized in the USATONS to be used in the WRMS.
2. Using non-lateral daymarks as crossing daymarks in the WRMS.
3. Replacing the black buoys in the USWMS with green buoys.
4. Removing cardinal marks from the USWMS.
5. Marking hazards in the USWMS with the appropriate lateral marks as in the USATONS.

##### **Early Participation**

The Coast Guard is consulting with the National Association of State Boating-Law Administrators and with users in the Second Coast Guard District, as well as with State maritime authorities, to gather information required for this proposed change.

##### **Solicitation of Views**

The Coast Guard solicits comments from all segments of the marine community and other interested persons on economic and other impacts and [suggested alternatives related to aids to navigation system] to adequately mark the Uniform State Waterways and the Western Rivers. Persons submitting comments should include their names and addresses, identify this docket [CG 94-091], identify their concern or concerns, state what impacts may result from one or more of the alternatives identified, suggest other alternatives, and provide reasons to support the suggested alternatives. The Coast Guard is particularly interested in receiving

information, views, data, and reasons on the following questions and areas of concern:

##### **1. WHAT WOULD BE THE ECONOMIC IMPACTS OF A PROPOSED CHANGE IN LIGHTING CHARACTERISTICS ON THE WESTERN RIVERS?**

Would users be adversely affected by having additional lighting characteristics within the WRMS?

What financial impact would this have?

Who are the persons most affected?

##### **2. WHAT OTHER FACTORS AFFECT A PROPOSED CHANGE IN LIGHTING?**

Is there any other information that you feel may be helpful in implementing this change with less impact on the affected persons?

##### **3. SHOULD CROSSING DAYBOARDS USED IN THE WRMS BE REPLACED BY THE NON-LATERAL DAYBOARDS USED IN THE USATONS?**

Should the currently used single-color crossing dayboards be replaced by the red-and-white or green-and-white non-lateral marks for better visibility?

##### **4. WHAT IS THE BEST WAY TO MARK OBSTRUCTIONS IN THE USWMS?**

Should cardinal marks be retained, or should the States adopt a system similar to that of the USATONS?

##### **5. SHOULD THE MEANING OF THE RED-AND-WHITE STRIPED BUOYS IN THE USWMS BE CHANGED SO SUCH BUOYS MARK SAFE WATER AS IN THE USATONS?**

Dated: December 20, 1995.

Rudy K. Peschel,

*Rear Admiral, U.S. Coast Guard, Chief, Office of Navigation Safety and Waterway Services.*  
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### **33 CFR Part 117**

**[CGD13-95-050]**

#### **Drawbridge Operation Regulations; South Slough, OR**

**AGENCY:** Coast Guard, DOT.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** At the request of the Oregon Department of Transportation (ODOT), the Coast Guard is considering an amendment to the regulations governing the operation of the South Slough Bridge at Charleston, Oregon. The proposed change would require one hour notice at all times when requesting openings of the drawspan of the bridge for the passage of vessels.

**DATES:** Comments must be received on or before February 27, 1996.